



AUTOMATIC LIQUID PACKAGING, INC.

July 20, 1999

2200 LAKE SHORE DRIVE WOODSTOCK, ILLINOIS 60098-7498 USA
TELEPHONE 815 338 9500 FACSIMILE 815 338 5504
<http://www.alp-bfs.com>

Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Extra Eye Drops

To Whom it may Concern:

Automatic Liquid Packaging Inc., (ALP) is a Contract Manufacturer of OTC Ophthalmic Eye Care Products, located in Woodstock, Illinois. We contract manufacture for retail companies such as Rite Aid, Walgreen's, Sentry, etc.

For approximately 8 - 10 years we have been manufacturing and distributing a line of eye drops manufactured by our internal Personal Care division of ALP in 0.5 and 1.0 fluid Ounce Sizes. This line of products is in compliance as outlined in **21 CFR 349**. The line consists of the following:

PRODUCT NAME

ACTIVE INGREDIENT

Extra Eye Drops

Tetrahydrozoline HCL
(a vasoconstrictor)
Polyethylene Glycol 400
(a demulcent)

All the active ingredients conform to USP and are in compliance to the percents of Active Ingredients allowed in **21 CFR 349**.

Automatic Liquid Packaging, Inc., is requesting an Exemption from the labeling requirements as described in Federal Register published March 17, 1999 entitled "**Over-The-Counter Human Drugs; Labeling Requirements**" for our 0.5 and 1.0 Fluid Ounce size container box. The reason for this is that when all the Agency required labeling statements are included on the back panel in the new format and Helvetica type size, there is no room for the additional FDA labeling requirements.

Please refer to the attached copies of the carton and immediate container labeling that is included in this Application. Note the Helvetica type size and arrangement of the required statements on the Principle Display Panel. In addition, note the placement of statements such as Storage requirements, Manufactured by, Bar coding, Tamper evident, and Eye Drop

98N-0337

APP3

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Container opening instructions Statements such as this also must appear on the outside package.

As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

As mentioned previously in the Request for Exemption, ALP is a Contract Manufacturer of OTC Ophthalmic Eye Drops for many Retail Distributors. If the Agency will allow the requested modifications to the Principle Display Panel as attached, we also request approval for the retail distributors we manufacture the same ophthalmic product line. These distributors are detailed in the list attached to this letter. As you could imagine, from time to time, ALP will acquire a new distributor. If the Agency allows the modified text for our in-house "Your Choice" line, as well as our current list of distributors, we respectfully request that any new distributors we add be allowed these same modifications. ALP commits that the information included on the Principle Display Panel and side panels would be identical as shown in the Attachments for all present and future distributors we manufacture this eye drop line.

Please contact me at (815) 338-9500 with any questions, or if you require any additional information.

Sincerely,

AUTOMATIC LIQUID PACKAGING, INC.



John Brda
Regulatory Affairs Manager

c Al Rothchild

.5 Oz. Extra Eye Drops

Logo

**Eye
Drops
Extra**

• Eye Lubricant
• Redness Reliever
Eye Drops

.5 fl. oz. (15 mL)

Sterile

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyethylene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.


Distributed by or Manufactured by

AE05-13-0000

1 Oz. Extra Eye Drops

Logo

**Eye
Drops
Extra**



- Eye Lubricant
- Redness Reliever Eye Drops

1 fl. oz. (30 mL)

Sterile

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyethylene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

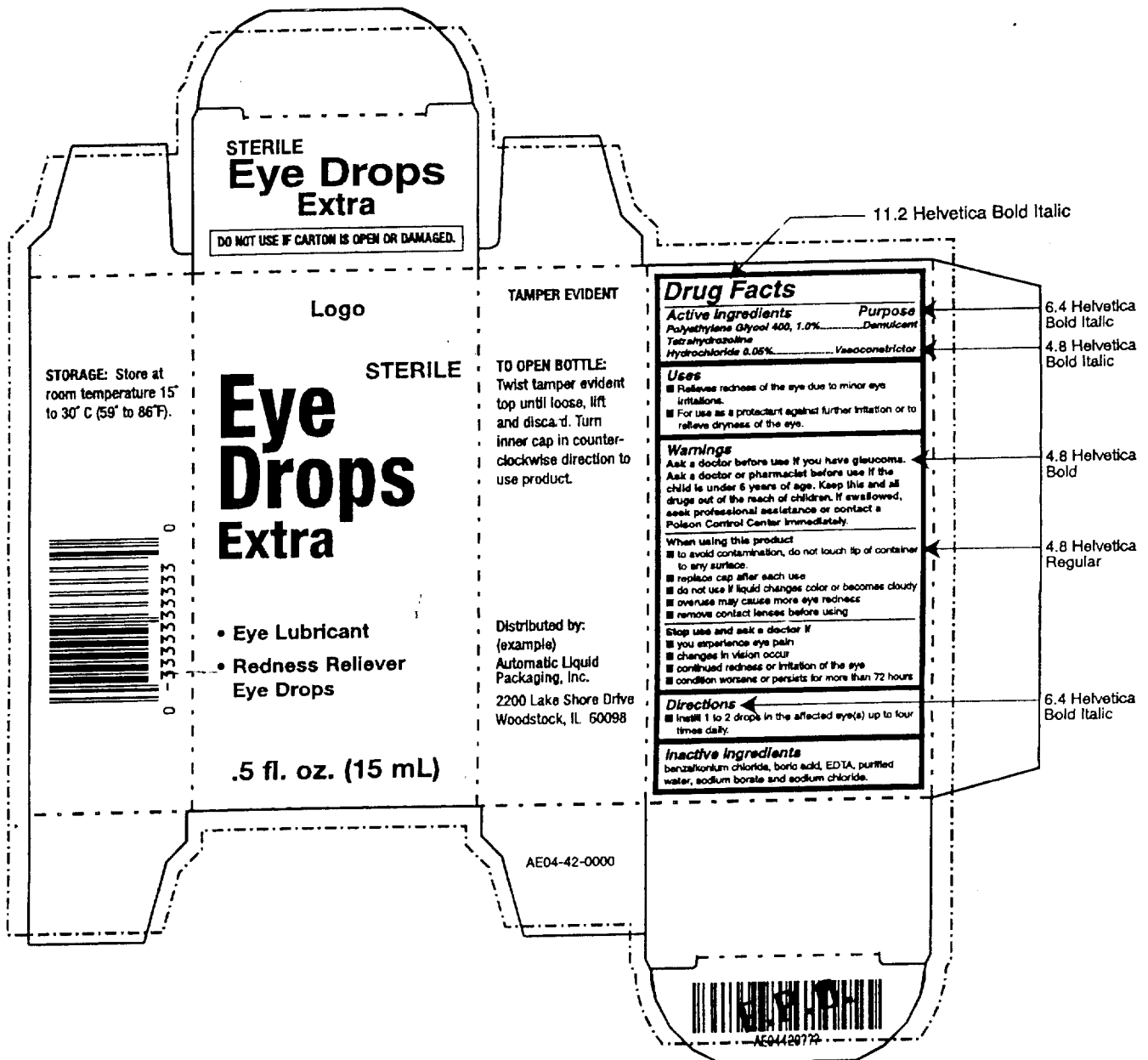
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

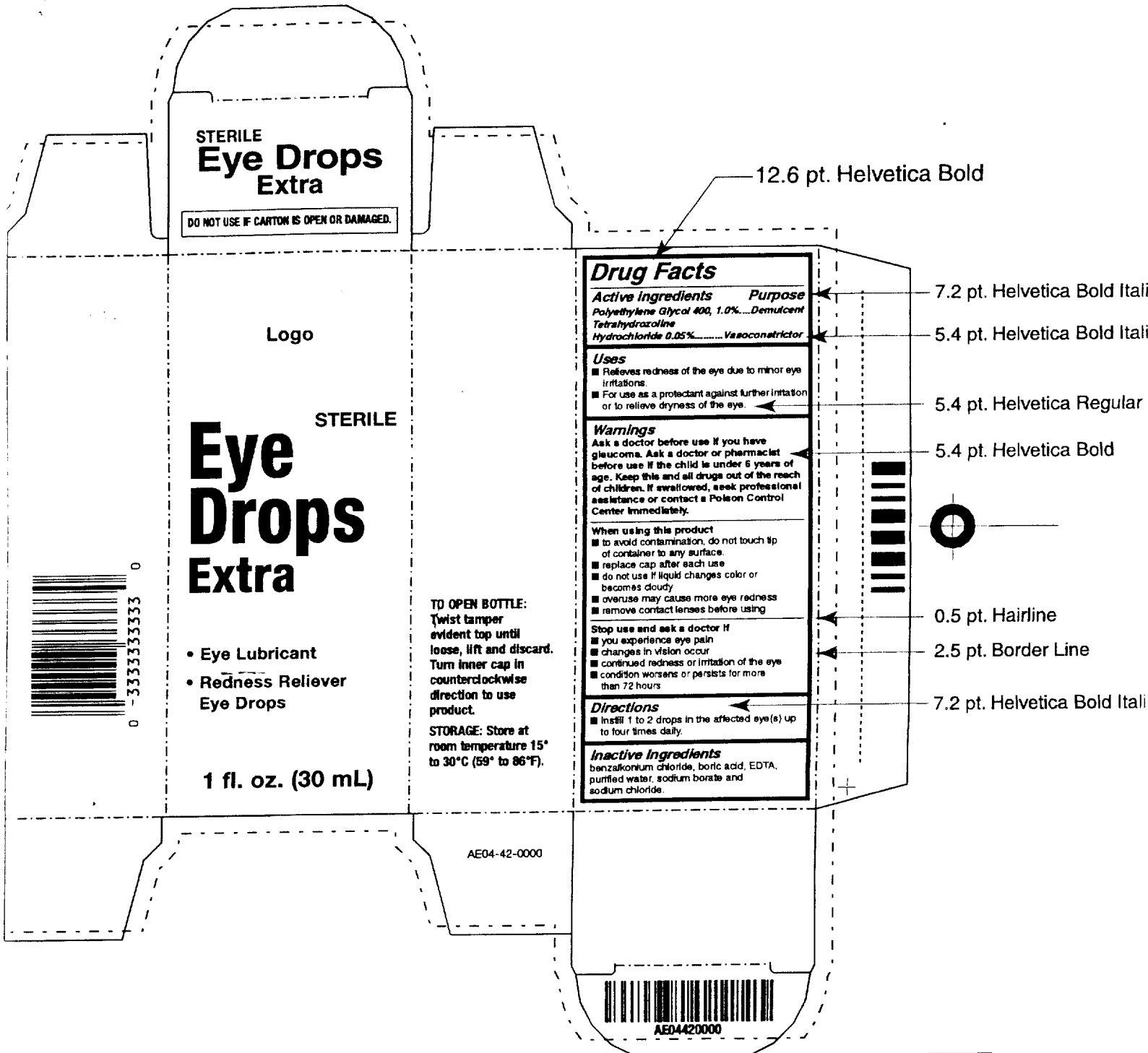
Distributed by or Manufactured by:

AE05-13-0000

.5 Oz. Extra Eye Drops



1 Oz. Extra Eye Drops



.5 Oz. Extra Eye Drops

Logo

**Eye
Drops
Extra**

- Eye Lubricant
- Redness Reliever

Eye Drops

.5 fl. oz. (15 mL)

Sterile

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: 1-Hydroxyethyl Glycol 400; 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.


Distributed by or Manufactured by

AZ05-13-0000

1 Oz. Extra Eye Drops

Logo

**Eye
Drops
Extra**



- Eye Lubricant
- Redness Reliever Eye Drops

1 fl. oz. (30 mL)

Sterile

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyethylene Glycol 400; 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

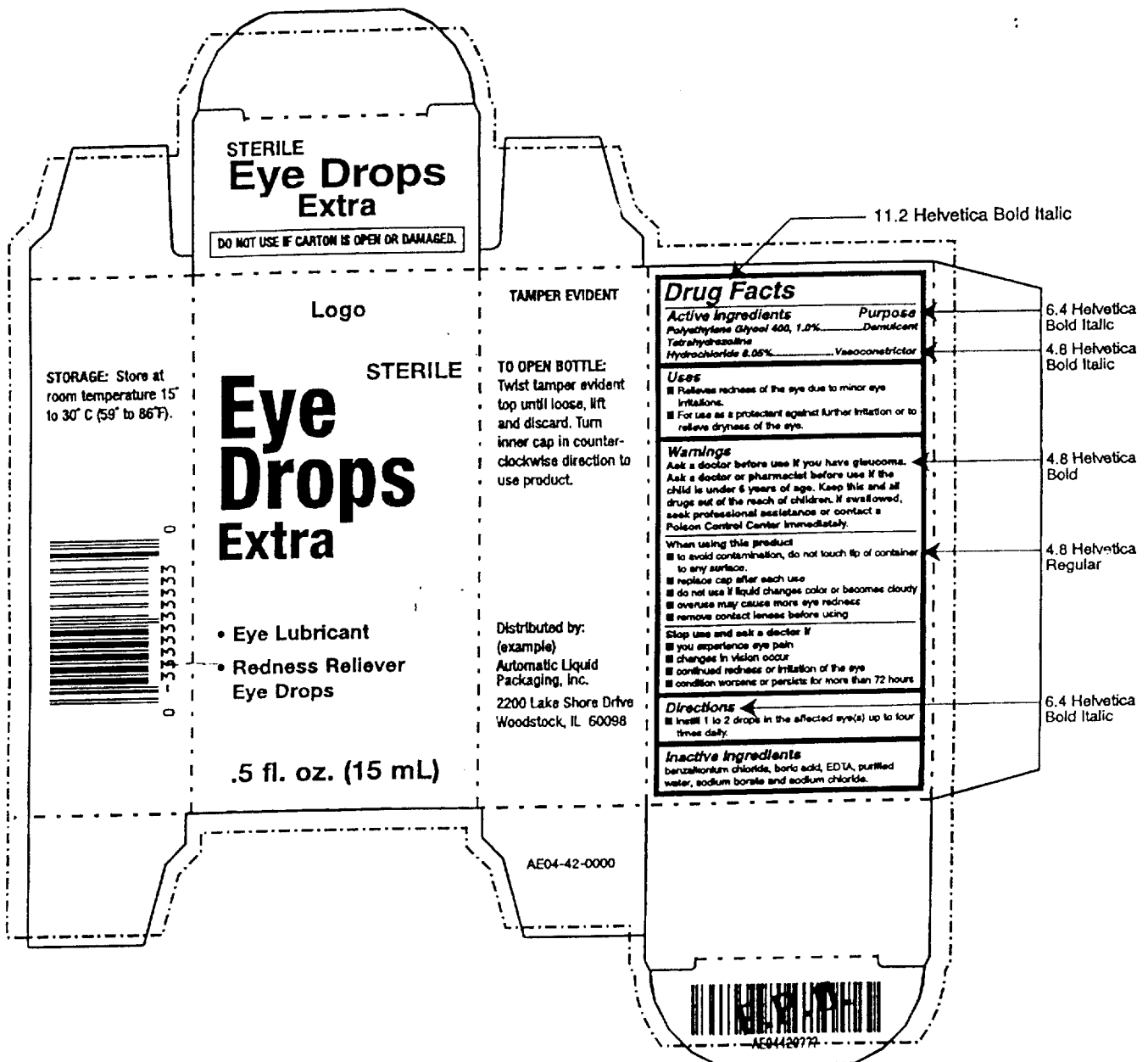
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

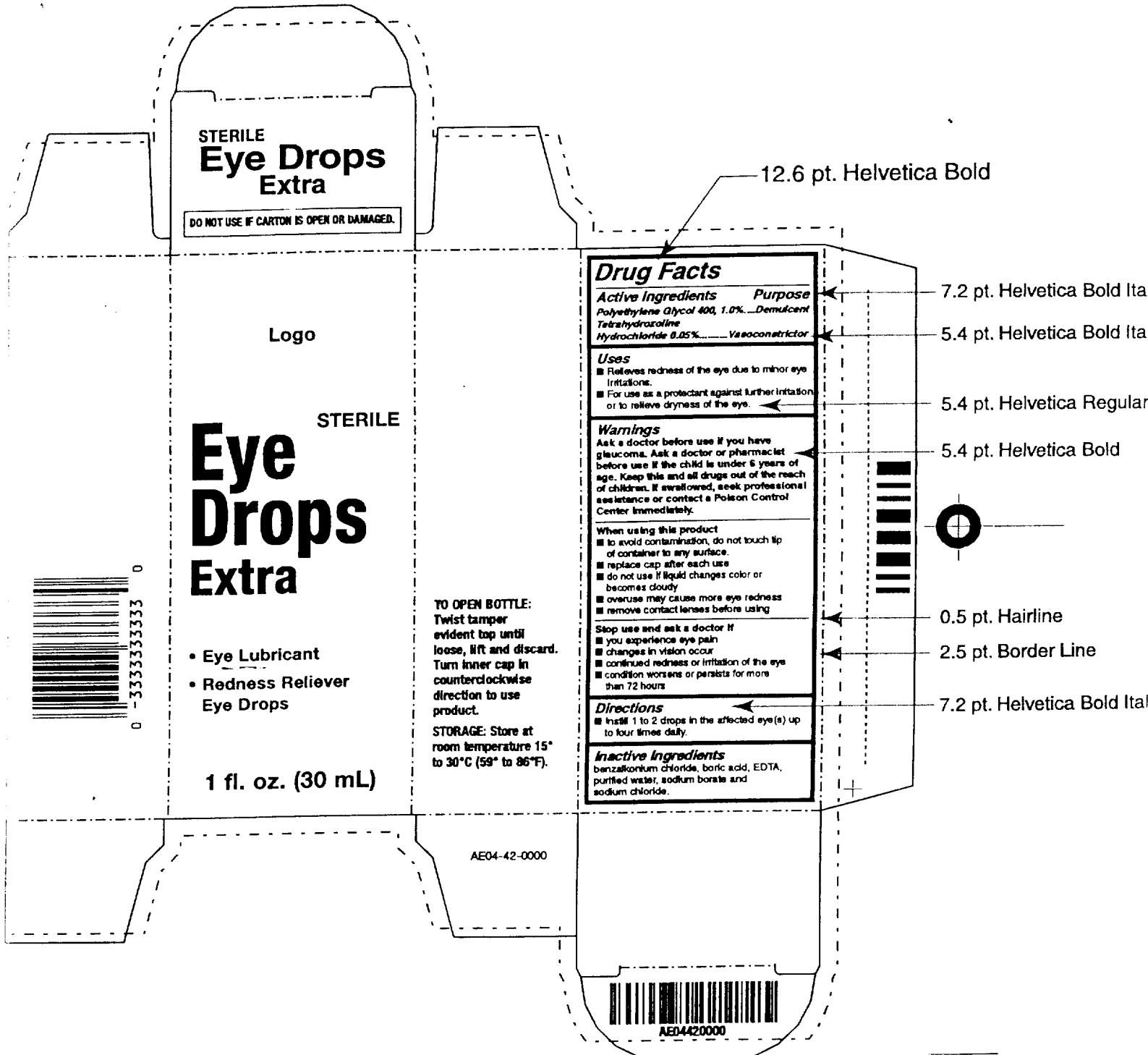
Distributed by or Manufactured by:

AE05-13-0000

.5 Oz. Extra Eye Drops



1 Oz. Extra Eye Drops



.5 Oz. Extra Eye Drops

Logo

**Eye
Drops
Extra**

• Eye Lubricant
• Redness Reliever
Eye Drops

.5 fl. oz. (15 mL)

Sterile

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.

DIRECTIONS: Insert 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polystyrene Glycol 400, 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.


Distributed by or Manufactured by

AE05-13-0000

1 Oz. Extra Eye Drops

Logo

**Eye
Drops
Extra**



- Eye Lubricant
- Redness Reliever Eye Drops

1 fl. oz. (30 mL)

Sterile

INDICATIONS: Relieves redness of the eye due to minor eye irritations. For use as a protectant against further irritation or to relieve dryness of the eye.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredients: Polyethylene Glycol 400: 1.0% and Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

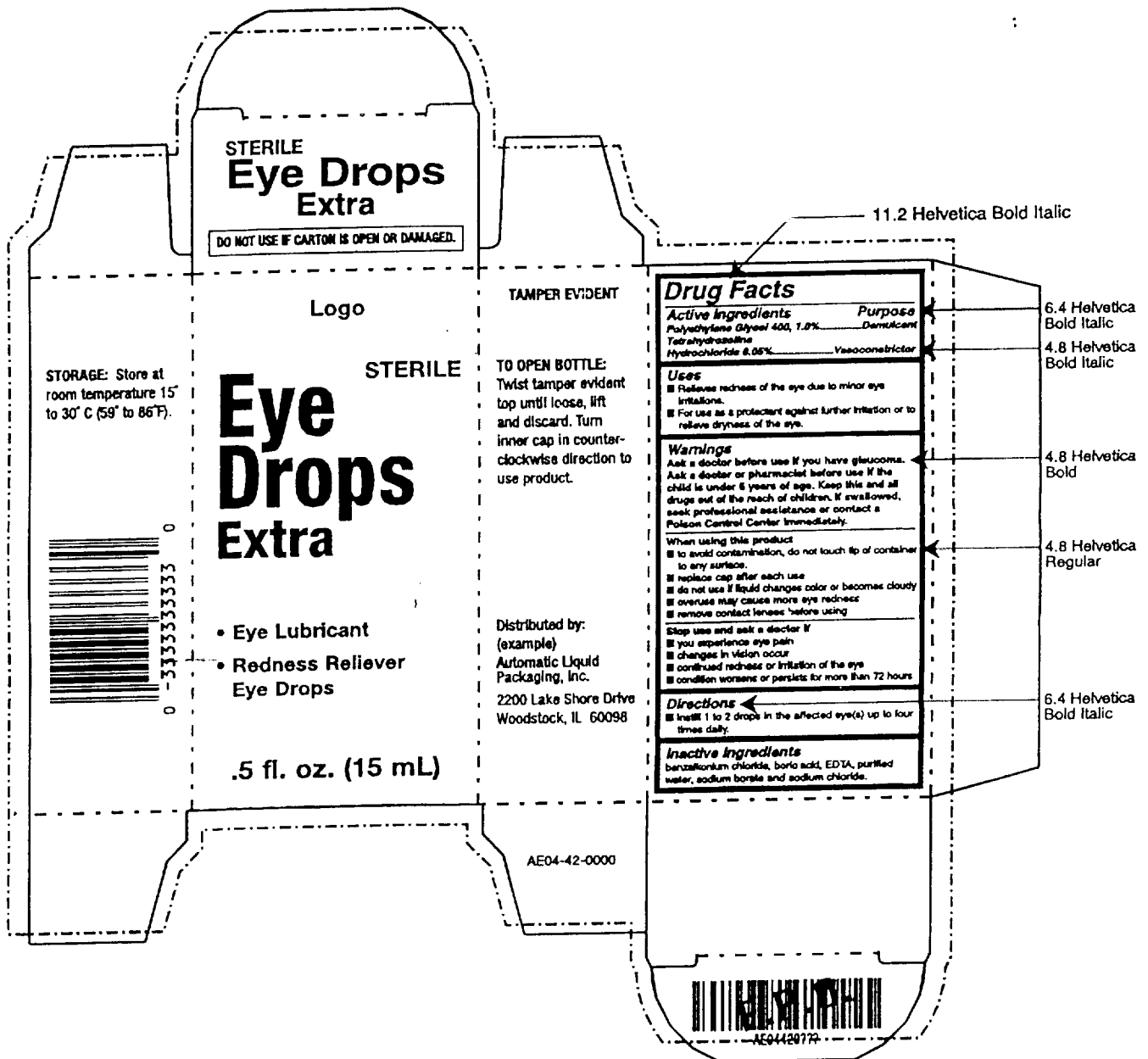
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by:

AE05-13-0000

.5 Oz. Extra Eye Drops



STERILE
**Eye Drops
Extra**

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

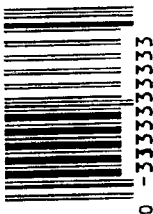
STERILE

**Eye
Drops
Extra**

- Eye Lubricant
- Redness Reliever
Eye Drops

.5 fl. oz. (15 mL)

STORAGE: Store at
room temperature 15°
to 30° C (59° to 86°F).



0 -3333333333

TAMPER EVIDENT

TO OPEN BOTTLE:
Twist tamper evident
top until loose, lift
and discard. Turn
inner cap in counter-
clockwise direction to
use product.

Distributed by:
(example)
Automatic Liquid
Packaging, Inc.
2200 Lake Shore Drive
Woodstock, IL 60098

AE04-42-0000

Drug Facts

Active Ingredients

Polyethylene Glycol 400, 1.0%
Tetrahydrozoline
Hydrochloride 0.05%

Purpose

Demulcent

Vasoconstrictor

Uses

- Relieves redness of the eye due to minor eye
irritations.
- For use as a protectant against further irritation or to
relieve dryness of the eye.

Warnings

Ask a doctor before use if you have glaucoma.
Ask a doctor or pharmacist before use if the
child is under 6 years of age. Keep this and all
drugs out of the reach of children. If swallowed,
seek professional assistance or contact a
Poison Control Center immediately.

When using this product

- To avoid contamination, do not touch tip of container
to any surface.
- replace cap after each use
- do not use if liquid changes color or becomes cloudy
- overuse may cause more eye redness
- remove contact lenses before using

Stop use and ask a doctor if

- you experience eye pain
- changes in vision occur
- continued redness or irritation of the eye
- condition worsens or persists for more than 72 hours

Directions

- Instill 1 to 2 drops in the affected eye(s) up to four
times daily.

Inactive Ingredients

benzalkonium chloride, boric acid, EDTA, purified
water, sodium borate and sodium chloride.

11.2 Helvetica Bold Italic

6.4 Helvetica
Bold Italic

4.8 Helvetica
Bold Italic

4.8 Helvetica
Bold

4.8 Helvetica
Regular

6.4 Helvetica
Bold Italic

1 Oz. Extra Eye Drops

